Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Mental health care in the perinatal period: Australian clinical practice guideline.

Bibliographic Source(s)

waiting for update

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Austin M-P, Highet N, Guidelines Expert Advisory Committee. Australian clinical practice guidelines for depression and related disorders -- anxiety, bipolar disorder and puerperal psychosis -- in the perinatal period. A guideline for primary health care professionals. Melbourne (Australia): beyondblue: the national depression initiative; 2011 Feb. 108 p. [293 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report Clinical Practice Guidelines We Can Trust.

= Poor = Fair = Good = Very Good = Excellent

Assessment	Standard of Trustworthiness
YES	Disclosure of Guideline Funding Source
	Disclosure and Management of Financial Conflict of Interests
	Guideline Development Group Composition

YES	Multidisciplinary Group
YES	Methodologist Involvement
▮▮▮▮▮	Patient and Public Perspectives
	Use of a Systematic Review of Evidence
▮▮▮▮▮	Search Strategy
▮▮▮▮▯	Study Selection
▮▮▮▮▮	Synthesis of Evidence
	Evidence Foundations for and Rating Strength of Recommendations
▮▮▮▮▯	Grading the Quality or Strength of Evidence
▮▮▮▮▮	Benefits and Harms of Recommendations
▮▮▮▮▮	Evidence Summary Supporting Recommendations
▮▮▮▯▯	Rating the Strength of Recommendations
▮▮▮▮▮	Specific and Unambiguous Articulation of Recommendations
▮▮▮▮▯	External Review
▮▮▮▮▯	Updating

Recommendations

Major Recommendations

The types of guidance (Evidence-based Recommendation [EBR], Consensus-based Recommendation [CBR] and Practice Point [PP]) and grades of recommendation (Strong and Conditional) are defined at the end of the "Major Recommendations" field.

Screening and Assessment

Training for Screening and Psychosocial Assessment

CBR - All health professionals providing care in the perinatal period should receive training in woman-centred communication skills, psychosocial assessment and culturally safe care.

Screening for Depression

EBR - Use the Edinburgh Postnatal Depression Scale (EPDS) to screen women for a possible depressive disorder in the perinatal period. (Strong)

EBR - Arrange further assessment of perinatal woman with an EPDS score of 13 or more. (Strong)

CBR - Complete the first antenatal screening as early as practical in pregnancy and repeat screening at least once later in pregnancy.

CBR - Complete the first postnatal screening 6 to 12 weeks after birth and repeat screening at least once in the first postnatal year.

CBR - For a woman with an EPDS score between 10 and 12, monitor and repeat the EPDS 2 to 4 weeks later as her score may increase subsequently.

CBR - Repeat the EPDS at any time in pregnancy and in the first postnatal year if clinically indicated.

CBR - For a woman with a positive score on Question 10 on the EPDS undertake or arrange immediate further assessment and, if there is any disclosure of suicidal ideation, take urgent action in accordance with local protocol/policy.

CBR - When screening Aboriginal and Torres Strait Islander women, consider language and cultural appropriateness of the tool.

CBR - Use appropriately translated versions of the EPDS with culturally relevant cut-off scores. Consider language and cultural appropriateness of the tool.

Screening for Anxiety

CBR - Be aware that anxiety disorder is very common in the perinatal period and should be considered in the broader clinical assessment.

CBR - As part of the clinical assessment, use anxiety items from screening tools (e.g., EPDS items 3, 4 and 5, Depression, Anxiety and Stress Scale [DASS] anxiety items and Kessler Psychological Distress Scale [K-10] items 2, 3, 5 and 6) and relevant items in structured psychosocial assessment tools (e.g., Antenatal Risk Questionnaire [ANRQ]).

Assessing Psychosocial Risk

PP - Assess psychosocial risk factors as early as practical in pregnancy and again after the birth.

EBR - If using a tool to assess psychosocial risk, administer the ANRQ. (Strong)

CBR - Undertake psychosocial assessment in conjunction with a tool that screens for current symptoms of depression/anxiety (i.e., the EPDS).

PP - Ensure that health professionals receive training in the importance of psychosocial assessment and use of a psychosocial assessment tool.

PP - Ensure that there are clear guidelines around the use and interpretation of the psychosocial tool/interview in terms of threshold for referral for psychosocial care and/or ongoing monitoring.

PP - Discuss with the woman the possible impact of psychosocial risk factors (she has endorsed) on her mental health and provide information about available assistance.

CBR - Consider language and cultural appropriateness of any tool used to assess psychosocial risk.

Assessing Mother-Infant Interaction

PP - Assess the mother-infant interaction as an integral part of postnatal care and refer to a parent-infant therapist as available and appropriate.

PP - Seek guidance/support from Aboriginal and Torres Strait Islander health professionals or bicultural health workers when assessing mother-infant interaction in Aboriginal and Torres Strait Islander or migrant and refugee women, to ensure that assessment is not informed by unconscious bias.

PP - Assess the risk of harm to the infant if significant difficulties are observed with the mother-infant interaction, the woman discloses that she is having thoughts of harming her infant and/or there is concern about the mother's mental health.

Assessing Risk of Suicide

PP - When a woman is identified as at risk of suicide (through clinical assessment and/or the EPDS), manage immediate risk, arrange for urgent mental health assessment and consider support and treatment options.

Supporting Emotional Health and Wellbeing

PP - At every antenatal or postnatal visit, enquire about the woman's emotional wellbeing.

PP - Provide women in the perinatal period with advice on lifestyle issues and sleep, as well as assistance in planning how this advice can be incorporated into their daily activities during this time.

Prevention and Treatment

General Principles in Prevention and Treatment

CBR - Provide all women with information about the importance of enquiring about, and attending to, any mental health problems that might arise across the perinatal period.

PP - If a woman agrees, provide information to and involve her significant other(s) in discussions about her emotional wellbeing and care throughout the perinatal period.

PP - Provide advice about the risk of relapse during pregnancy and especially in the early postpartum period to women who have a new, existing or past mental health condition and are planning a pregnancy.

PP - For women with schizophrenia, bipolar disorder or borderline personality disorder, a multidisciplinary team approach to care in the perinatal period is essential, with clear communication, advance care planning, a written plan, and continuity of care across different clinical settings.

PP - Wherever possible, assessment, care and treatment of the mother should include the baby.

PP - Where possible, health professionals providing care in the perinatal period should access training to improve their understanding of care for women with schizophrenia, bipolar disorder and borderline personality disorder.

General Principles in the Use of Pharmacological Treatments

PP - Discuss the potential risks and benefits of pharmacological treatment in each individual case with the woman and, where possible, her significant other(s).

PP - Ensure that women are aware of the risks of relapse associated with stopping medication and that, if a medication is ceased, this needs to be done gradually and with advice from a mental health professional.

PP - Discuss treatment (medication and psychological) options that would enable a woman to breastfeed if she wishes and support women who choose not to breastfeed.

PP - Ideally, treatment with psychoactive medications during pregnancy would involve close liaison between a treating psychiatrist or, where appropriate, the woman's GP, and her maternity care provider(s). In more complex cases, it is advisable to seek a second opinion from a perinatal psychiatrist.

PP - When exposure to psychoactive medications has occurred in the first trimester – especially with anticonvulsant exposures – pay particular attention to the 18–20 week ultrasound due to the increased risk of major malformation.

pp - Plan for pharmacological review in the early postpartum period for women who cease psychotropic medications during pregnancy.

CBR - Arrange observation of infants exposed to psychoactive medications in pregnancy for the first three days postpartum.

Postnatal Care and Support

PP - In planning postnatal care for women with schizophrenia, bipolar disorder, severe depression or borderline personality disorder, take a coordinated team approach to parent and infant mental health care and pre-arrange access to intensive maternal child health care.

PP - When caring for mothers with severe mental illness, including borderline personality disorder, it is important to ensure that child protection risks are understood and addressed, if necessary.

CBR - If a mother with a severe postnatal episode requires hospital admission, avoid separation from her infant with coâ€˜admission to a specialist mother-baby unit where facilities are available and appropriate.

Depressive and Anxiety Disorders

Psychosocial Support and Psychological Approaches

EBR - Provide structured psychoeducation to women with symptoms of depression in the perinatal period. (Strong)

EBR - Advise women with symptoms of depression in the postnatal period of the potential benefits of a social support group. (Conditional)

EBR - Recommend individual structured psychological interventions (cognitive behavioural therapy or interpersonal psychotherapy) to women with mild to moderate depression in the perinatal period. (Strong)

CBR - Advise women with symptoms of depression in the perinatal period of the potential benefits of facilitated selfâ€˜help.

EBR - Advise women with depression or anxiety disorder in the postnatal period of the possible benefits of directive counselling. (Conditional)

CBR - Advise women with diagnosed post-traumatic stress disorder of the potential benefits of post-traumatic birth counselling if they are experiencing depressive symptoms.

CBR - For women who have or are recovering from postnatal depression and are experiencing mother–infant relationship difficulties, consider provision of or referral for individual mother–infant relationship interventions.

Complementary Therapies

EBR - Advise women that omega-3 fatty acid supplementation does not appear to improve depression symptoms but is not harmful to the fetus or infant when taken during pregnancy or while breastfeeding. (Conditional)

CBR - Advise pregnant women that the evidence on potential harms to the fetus from St John's Wort is limited and uncertain and its use during pregnancy is not recommended.

CBR - Advise pregnant women that potential harms to the fetus from Gingko biloba have not been researched and its use during pregnancy is not recommended.

Pharmacological Treatments for Depressive and Anxiety Disorders

EBR - Consider the use of selective serotonin reuptake inhibitors (SSRIs) as first-line treatment for moderate to severe depression and/or anxiety in pregnant women. (Conditional)

PP - Before choosing a particular SSRI for pregnant women, consider the woman's past response to SSRI treatment, obstetric history (e.g., other risk factors for miscarriage or preterm birth) and any factors that may increase risk of adverse effects.

EBR - Use SSRIs as first-line treatment for moderate to severe depression in postnatal women. (Strong)

PP - Before prescribing SSRIs to women who are breastfeeding, consider the infant's health and gestational age at birth.

CBR - Consider the short-term use of benzodiazepines for treating moderate to severe symptoms of anxiety while awaiting onset of action of an SSRI or tricyclic antidepressants (TCA) in pregnant or postnatal women.

PP - Use caution in repeated prescription of long-acting benzodiazepines around the time of the birth.

PP - Use caution in prescribing non-benzodiazepine hypnotics (z-drugs) to pregnant women for insomnia.

PP - Doxylamine, a Category A drug in pregnancy, may be considered for use as a first-line hypnotic in pregnant women who are experiencing moderate to severe insomnia.

Psychological Intervention for Women with Moderate to Severe Anxiety and Depressive Disorders

CBR - Advise women with moderate to severe anxiety and depressive disorders that psychological interventions are a useful adjunct, usually once medications have become effective.

Severe Mental Illnesses

Antipsychotics

EBR - Consider the use of antipsychotics for treating psychotic symptoms in pregnant women. (Conditional)

CBR - Use caution when prescribing any antipsychotic to pregnant women, particularly for women with a propensity for weight gain and metabolic syndrome.

CBR - If women commence or continue antipsychotic treatment during pregnancy, monitor them for excessive weight gain and the development of gestational diabetes and refer them for advice on weight management as required.

CBR - Do not initiate use of clozapine in pregnant women.

PP - Use clozapine with caution in women who are breastfeeding and monitor the infant's white blood cell count weekly for the first six months of life.

Anticonvulsants

PP - Given their teratogenicity, only consider prescribing anticonvulsants (especially valproate) to women of childâ€‘bearing age if effective contraception is in place.

PP - Once the decision to conceive is made, if the woman is on valproate wean her off this over 2 to 4 weeks, while adding in high-dose folic acid (5 mg/day) which should continue for the first trimester.

EBR - Do not prescribe sodium valproate to women of childbearing age. (Strong)

CBR - Use great caution in prescribing anticonvulsants as mood stabilisers for pregnant women and seek specialist psychiatric consultation when doing so.

CBR - If anticonvulsants are prescribed to a woman who is breastfeeding, arrange close monitoring of the infant and specialist neonatologist consultation where possible.

CBR - If lithium is prescribed to pregnant women, ensure that maternal blood levels are closely monitored and that there is specialist psychiatric consultation.

PP - If lithium is prescribed to a pregnant woman, reduce the dose just prior to the onset of labour and aim to recommence treatment immediately after the birth at a pre-pregnancy dose.

CBR - Where possible, avoid the use of lithium in women who are breastfeeding.

Borderline Personality Disorder

PP - For women with borderline personality disorder who have often experienced complex trauma, trauma-informed care and specific support for health professionals in dealing with challenging behaviours is a

priority.

PP - Advise women with borderline personality disorder who are planning a pregnancy of the additional challenges of parenting associated with their emotional dysregulation, and the importance of ongoing support during and after pregnancy.

CBR - Where possible and appropriate, provide women with borderline personality disorder with structured psychological therapies that are specifically designed for this condition and conducted by adequately trained and supervised health professionals.

PP - Encourage pregnant or postnatal women with borderline personality disorder to undertake mindfulness and/or relaxation training to assist in managing their emotional dysregulation.

CBR - As far as possible, do not use pharmacological treatments as the primary therapy for borderline personality disorder, especially in pregnant women.

Electroconvulsive Therapy

CBR - Consider electroconvulsive therapy (ECT) when a postnatal woman with severe depression has not responded to one or more trials of antidepressants of adequate dose and duration.

CBR - Consider ECT as first-line treatment for postnatal women with severe depression especially where there is a high risk of suicide or high level of distress; when food or fluid intake is poor; and in the presence of psychotic or melancholic symptoms.

PP - In pregnant women, ECT should be only be undertaken in conjunction with close fetal monitoring (using cardiotocography to monitor fetal heart rate) and access to specialist maternal-fetal medical support.

Definitions

Types of Guidance

- Evidence-based Recommendations (EBR) – a recommendation formulated after a systematic review of the evidence, with a clear linkage from the evidence base to the recommendation using Grading of Recommendations Assessment, Development and Evaluation (GRADE) methods
  - Strong – implies that most/all individuals will be best served by the recommended course of action; used when confident that desirable effects clearly outweigh undesirable effects or, conversely, when confident that undesirable effects clearly outweigh desirable effects
  - Conditional – implies that not all individuals will be best served by the recommended course of action; used when desirable effects probably outweigh undesirable effects; used when undesirable effects probably outweigh desirable effects
- Consensus-based Recommendation (CBR) – a recommendation formulated in the absence of quality evidence, after a systematic review of the evidence was conducted and failed to identify sufficient admissible evidence on the clinical question
- Practice Point (PP) – advice on a subject that is outside the scope of the search strategy for the systematic evidence review, based on expert opinion and formulated by a consensus process

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Mental health conditions in the perinatal period including:

- Depressive and anxiety disorders
- Severe mental illness (bipolar disorder, postpartum psychosis, schizophrenia)
- Borderline personality disorder

Guideline Category

Counseling

Evaluation

Management

Prevention

Risk Assessment

Screening

Treatment

Clinical Specialty

Family Practice

Nursing

Obstetrics and Gynecology

Pediatrics

Psychiatry

Psychology

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Nurses

Other

Patients

Physician Assistants

Physicians

Psychologists/Non-physician Behavioral Health Clinicians

Public Health Departments

Social Workers

Guideline Objective(s)

To summarise the current evidence for screening for depressive and anxiety symptoms and risk factors and preventing and treating a range of mental health conditions in the perinatal period

Note: The guideline does not cover:

The diagnosis or specifics of managing mental health conditions in the perinatal period
Routine assessment of specific social and lifestyle factors that affect perinatal outcomes and may also be associated with mental health.

Target Population

All pregnant or postnatal women, with the postnatal period being defined as the 12 months following birth

Note: As this guideline also provide an assessment of the harms associated with interventions used for the treatment or prevention of perinatal mental health issues, the population also encompasses the offspring of these women. Attention is also given to women with a history of mental health issues who might be planning a pregnancy.

Interventions and Practices Considered

Screening/Assessment

- Training for healthcare professionals
- Screening for depression (Edinburgh Postnatal Depression Scale [EPDS])
- Screening for anxiety using appropriate screening tools
- Assessment of
  - Psychosocial risk (Antenatal Risk Questionnaire [ANRQ], EPDS)
  - Mother-infant interaction
  - Risk of suicide
- Support for emotional health and wellbeing

Prevention/Treatment

- Provision of information about mental health problems that might arise across the perinatal period
- Discussion of risks and benefits of pharmacological treatment
- Observation of infants exposed to psychoactive medications in pregnancy
- Postnatal care and support
  - Access to intensive maternal child health care
  - Co-admission to specialist mother-baby hospital unit
- Structured psychoeducation
- Psychosocial support and psychological approaches
  - Social support groups
  - Facilitated selfâ€‘help
  - Directive counselling
  - Post-traumatic birth counselling
  - Individual structured psychological interventions (cognitive behavioural therapy, interpersonal psychotherapy)
  - Referral for individual mother–infant relationship interventions
  - Mindfulness and/or relaxation training
- Complimentary therapies: omega-3 fatty acid supplementation
- Pharmacological treatment
  - Selective serotonin reuptake inhibitors (SSRIs)
  - Benzodiazepines
  - Non-benzodiazepine hypnotics (doxylamine)
  - Antipsychotics
  - Anticonvulsants

Electroconvulsive therapy (ECT)

Note: The following complimentary therapies were considered but not recommended: St. John's Wort, Gingko biloba.

Major Outcomes Considered

- Prevalence and impact of maternal mental health conditions
- Risk of depression and anxiety disorders
- Risk of suicide
- Risk to infant
- Symptoms of depression in the perinatal period
- Risk of relapse
- Sensitivity, specificity, and positive predictive value of assessment tools
- Quality of the mother-infant interaction/relationship
- Safety of pharmacologic agents in pregnancy and breastfeeding
- Adverse effects of pharmacologic agents
- Cost-effectiveness and cost of care

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Search Methods

Searches were conducted in the MEDLINE, EMBASE and PsycINFO databases, and also in CINAHL for psychosocial assessment and screening (via the OVID and/or Embase.com interfaces), various databases of the Cochrane Library, and included examination of the reference lists of included systematic reviews (SRs) and individual studies. Searches were conducted between June 2016 and April 2017.

The full search strategies appear in the Technical Report and Appendices (see the "Availability of Companion Documents" field).

Evidence Selection Criteria

The main inclusion/exclusion criteria for each of the research question types were as follows. More detailed PICO (Population, Intervention, Comparator, Outcomes) criteria used to inform the literature search are included in more detail in the Technical Report.

Psychosocial Assessment and Screening

Target population – all pregnant or postnatal women (psychosocial assessment), or pregnant or postnatal women with no known diagnosis of depression or anxiety (screening)
Study design – prospective, controlled studies reporting predictive accuracy (psychosocial assessment) or diagnostic accuracy (screening)
Comparisons – subsequent manifestation of mental health issues (psychosocial assessment), or any standard clinical/diagnostic interview as a reference standard (screening)
Language – limited to English

Effectiveness of Interventions

Target population – pregnant or postnatal women diagnosed with a mental health problem, or considered to be at risk of developing a mental health problem
Study design – SRs of randomized controlled trials (RCTs), or individual RCTs if no SR or SR out of date
Interventions – Psychosocial, psychological, pharmacological, complementary or physical therapies used to treat or prevent mental health problems in pregnant or postnatal women
Comparisons – no treatment/placebo/treatment as usual or active treatment
Language – limited to English

Harms of Interventions

Target population – pregnant or postnatal women diagnosed with a mental health problem, or considered to be at risk of developing a mental health problem, or a fetus, infant or child of a mother exposed to a pharmacological, complementary or physical therapy
Study design – SRs of RCTs (if available), SRs of observational studies, or individual observational studies if no SR or SR out of date or unsuitable
Comparisons – no treatment/exposure or active treatment
Language – limited to English

Number of Source Documents

See the "Exclusion of studies" sections in Technical Report (see the "Availability of Companion Documents" field).

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Refer to the Technical Report (see the "Availability of Companion Documents" field) for the various rating schemes used for individual study quality assessment, overall quality assessment, and a discussion of Grading of Recommendations Assessment, Development, and Evaluation (GRADE).

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Strengths and Limitations of the Evidence

The strengths and limitations of the evidence have been considered from the perspective of the individual studies and the body of evidence aggregated across all the studies. Wherever possible validated methods have been used to assess:

Study design(s)
Study methodology limitations (sampling, blinding, allocation concealment, analytical methods)

Appropriateness/relevance of primary and secondary outcomes considered
Consistency of results across studies
Direction of results across studies
Magnitude of benefit versus magnitude of harm
Applicability to practice context

Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology was used to determine the quality of the evidence available for each intervention/outcome. The majority of the evidence for fetal harms was considered generally to be of very low or inadequate quality. It should be noted that the category 'inadequate' was added for the review to better reflect the broad range of quality that would have been considered very low if GRADE methods had been adhered to. A discussion of this adaptation of GRADE methodology can be found in Part D of the Technical Report (see the "Availability of Companion Documents" field).

In addition, no GRADE methods could be identified for the assessment of psychometric instruments. Consequently, a hybrid method was developed for quality appraisal of psychosocial assessment instruments. This method was based on accepted psychometric properties and Quality Assessment of Diagnostic Accuracy Studies-2 (QUADAS-2) principles and is described in detail in Part B of the Technical Report.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Formulation of Recommendations

As evidence reviews on specific topics were completed they were considered by the Expert Working Group (EWG) and the relevant expert committee(s) as appropriate. The interpretation and implications of the review findings were discussed, and then evidence-based recommendations (EBRs) developed once consensus was reached. The strength of the EBRs was agreed at this point. Once a group of related EBRs and consensus-based recommendations (CBRs) was developed, the EWG deliberated on the need for practice points to highlight important aspects of care.

The expert committees provided specific expertise to support the EWG. The Harms Expert Committee carried out the initial review of the harms systematic reviews and proposed recommendations for consideration and approval by the EWG.

Once recommendations had been developed across all types of intervention, the Low Prevalence Expert Committee proposed recommendations relevant to women with bipolar disorder, postpartum psychosis, schizophrenia or borderline personality disorder in the perinatal period. This process involved explicit consideration of relevant, recent Australian Guidelines for mood disorder, schizophrenia, and borderline personality disorder in general populations.

Rating Scheme for the Strength of the Recommendations

Types of Guidance

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Practice Point (PP) – advice on a subject that is outside the scope of the search strategy for the systematic evidence review, based on expert opinion and formulated by a consensus process

Cost Analysis

Cost-effectiveness of Perinatal Mental Health Screening

To address potential resourcing implications of screening, a separate search was undertaken to identify economic evaluations/cost-effectiveness analyses of perinatal screening for depression or anxiety. Full details of the literature search are included in Section B8.1 in the Technical Report (see the "Availability of Companion Documents" field).

Cost-effectiveness of Perinatal Depression Screening

No cost-effectiveness data were identified that are directly relevant to the Australian context, due to differences in approach to screening, pathways to care, and differences in input costs.

An analysis conducted for the UK National Institute for Health Research (NIHR)-Health Technology Assessment Programme concluded that formal identification of postnatal depression (PND) using the Edinburgh Postnatal Depression Scale (EPDS) (with cut points ranging 12–16) do not represent value for money for the UK National Health Service, mainly due to the potential additional costs of managing women incorrectly diagnosed as depressed.

In contrast, a more recent cost-effectiveness analysis for National Institute for Health and Care Excellence (NICE) found that the use of a brief case identification tool (that is, the Whooley questions), followed by the use of a more formal method (such as the EPDS or PHQ-9), appears to be the most cost-effective approach in the identification of depression in the postnatal period.

Likewise, a recent study from a Medicaid payer perspective assessed the cost-effectiveness of a two-stage approach to screening, whereby all women were screened with the short-form EPDS and then only those women who were positive received further screening with the 10-item long-form. The analysis found that routine screening and treatment of PND is a cost-effective intervention under a wide range of willingness-to-pay thresholds and should be considered as part of usual postnatal care.

In Canada, a large randomised controlled trial (RCT) is underway to assess the clinical and cost-effectiveness of usual prenatal care plus an integrated intervention comprising online psychosocial assessment, referral and online cognitive behavioural therapy (CBT). The integrated care model incorporates online screening for prenatal depression using the EPDS, together with online psychosocial risk assessment using the Antenatal Risk Questionnaire (ANRQ-R). Women who meet the criteria for CBT based on ANRQ-R and EPDS scores are then referred to online CBT, involving six, 30-minute interactive modules over 6 to 8 weeks. An early feasibility study found that women were very receptive to online screening. According to the study protocol, the economic evaluation will involve a within-trial cost-effectiveness analysis comparing the integrated intervention 'package' with usual prenatal care. The perspective of the primary analysis will be that of the Canadian health and social care budget, with a secondary analysis that adopts a societal perspective incorporating personal and productivity costs.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

External Review

Independent AGREE Appraisal

Two independent methodologists were engaged to critically appraise the Guideline using the Appraisal of Guidelines for Research & Evaluation (AGREE) II instrument. This involved assessing the Guideline over a number of domains using the *AGREE-II User's Manual*. The appraisal from both reviewers was generally positive, with combined domain scores as described in the original guideline document.

Independent Peer Review

Peer review was sought from clinicians with expertise in perinatal care. No substantive changes were made to the Guideline as a result of peer review.

Public Consultation

The draft guidelines were released for a 30-day public consultation, as required in the National Health and Medical Research Council (NHMRC) Act, 1992 (as amended), so that the final guidelines could be submitted for approval by the Chief Executive Officer (CEO) of the NHMRC, under Item 14A *Approval by CEO of guidelines for third parties*, under the Act.

Public consultation on the draft Guideline was conducted from 5 June to 4 July 2017.

The consultation draft was disseminated through COPE company members (see the original guideline document for a list).

In addition, representatives of state and territory health departments were contacted and advised of the public consultation.

A submission summary was developed that documented public submissions received and responses from the Expert Working Group (EWG). This document is available from the COPE Web site.

Over the consultation period and the following 17 days, 30 submissions were received. Of these, six were from individuals and the remainder from organisations (including professional colleges, associations and societies; state/territory health departments; research centres and consumer organisations). One individual submission was from a consumer with a lived experience of antenatal psychosis and another from a consumer representative. Two pairs of submissions were duplicate or raised the same points with slightly different wording. The Australian College of Mental Health Nurses and PANDA (a consumer organisation) advised that they would not be providing a submission as they had been represented on the EWG and felt that their comments had been acknowledged in that forum.

Following the consultation period, submissions, a report of submissions and a revised draft of the Guideline with editorial advice (developed by the Co-Chairs and the technical writer) were circulated to the EWG by email and feedback sought. All EWG members provided feedback on this initial revision and there was general consensus on the suggested changes. The EWG feedback was collated and informed the further development of the draft Guideline. Final drafts of the Guideline and submission report were then circulated to the EWG for sign-off.

Refer to the original guideline document for substantive comments provided in submissions and the EWG response. The submission report includes all comments provided through submissions and The EWG response.

Publication Approval

The guideline recommendations were approved by the Chief Executive Officer of NHMRC on 17 October

2017 under section 14A of the NHMRC Act 1992. In approving the guideline recommendations, NHMRC considers that they meet the NHMRC standard for clinical practice guidelines. This approval is valid for a period of five years.

NHMRC is satisfied that the guideline recommendations are systematically derived, based on the identification and synthesis of the best available scientific evidence, and developed for health professionals practising in an Australian health care setting.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

It is hoped that the implementation of the recommendations in this Guideline will:

- Increase rates of screening for depressive and anxiety disorders and reduce the severity of disorders (through early identification) and hence the need for specialist care
- Lead to consistent approaches to assessment of psychosocial risk
- Support the development of clear referral pathways for health professionals to refer women to suitably qualified health professionals and/or online treatments for the provision of timely recommended psychological treatments
- Support a safe and balanced use of pharmacological treatments in the perinatal period.

Consideration of Harms and Benefits

The evidence reviews (see the "Availability of Companion Documents" field) explicitly considered health benefits and harms. The trade-off between benefits and harms is articulated in the rationale for each evidence-based recommendation.

Recommendations on the use of psychosocial and psychological interventions were based primarily on evidence of the effectiveness, because they do not cause direct harm to the fetus, infant or child.

Recommendations on the use of pharmacological, complementary and selected physical interventions were to be based on a tradeoff between effectiveness and harm; however, there was very little evidence of effectiveness for these interventions in the perinatal population. The only evidence available was for antidepressants (suggesting it may improve postnatal depression) and omega-3 fatty acids (where it appeared to have no effect on depression).

Potential Harms

Consideration of Harms and Benefits

The evidence reviews (see the "Availability of Companion Documents" field) explicitly considered health benefits and harms. The trade-off between benefits and harms is articulated in the rationale for each evidence-based recommendation.

The harms most likely to effect recommendations were major and cardiac malformations, and

neurodevelopmental harms. Due to its strong association with major and cardiac malformation, and adverse cognitive outcome, as well as a lack of evidence of effectiveness in pregnant or postpartum women with, or at risk of developing, a mental health problem, the prescribing of sodium valproate in all women of childbearing age, was strongly recommended against. The evidence of harm associated with carbamazepine, and the lack of evidence for lamotrigine led to a consensus-based recommendation to prescribe anticonvulsants with great caution during pregnancy.

While there were a number of pregnancy and birth outcomes found to be associated with pharmacological therapies (including miscarriage, preterm birth, poor neonatal adaptation syndrome, respiratory distress, convulsions and persistent pulmonary hypertension), these were not directly captured in any recommendations; instead, a Practice Point notes that the potential risks of treatment (including the risk of relapse), as well as the benefits, be discussed with women.

There was little evidence available on the side effects of the pharmacological, complementary and physical interventions assessed; these treatments are all used regularly in clinical practice and as such their side-effect profiles are well established. However, based on a known side-effect of clozapine, agranulocytosis, a consensus-based recommendation states that its use should not be initiated during pregnancy due to the potential harm to the infant.

Contraindications

Contraindications

- Do not initiate use of clozapine in pregnant women.
- Do not prescribe sodium valproate to women of childbearing age.

Qualifying Statements

Qualifying Statements

- This is a general guide to appropriate practice, to be followed subject to the relevant clinician's judgement in each individual case. The Centre of Perinatal Excellence (COPE) has taken all reasonable steps to ensure that the Guidelines is based on, and accurately represent, the best available published evidence on key areas of antenatal care. However, COPE does not accept any legal liability for any loss, damage, costs or expenses that may result from reliance on the information and recommendations contained in this Guideline.
- It should be noted that the information on pharmacological treatments in this section is based on the best available evidence, up to September 2016 (the cut-off for the systematic literature review conducted for this Guideline). The evidence base is evolving as new research frequently emerges.
- This publication reflects the views of the authors and not necessarily the views of the Australian Government.

Implementation of the Guideline

Description of Implementation Strategy

Dissemination and Implementation

As Australia's peak body in Perinatal Mental Health, the Centre of Perinatal Excellence (COPE) will provide leadership and collaborate with its membership to support and promote the implementation of the final

Guideline.

The final complete Guideline, together with a series of companion documents and resources, will be disseminated broadly through the implementation of the following strategies.

Overarching

- Production of Guideline and companion documents for health professionals and consumers, which will be available from the COPE Web site
- Placement of Guideline on key Web sites (COPE, Colleges, Perinatal Anxiety and Depression Australia [PANDA] and the Commonwealth Government)
- E-dissemination of the Guideline through all professional bodies
- National and targeted media releases to announce the release of the new Perinatal Guideline

Health Professionals (Targeted)

- Writing and dissemination of newsletters and articles to disseminated across all professional bodies (COPE Membership) to inform respective college members of the new Guideline and where and how to access them
- Presentation of key recommendations at key meetings/conferences, including the Marce Australasian Conference in September 2017
- Publication of journal articles for journals commonly referred to by health practitioners

To support implementation, a free online training program will accompany the release of the Guideline. This will facilitate education for health professionals and include coverage of all guideline recommendations and good practice points. In addition, all companion documents that have been developed for health professionals and consumers/carers will be embedded into the online program to direct people to specific information on each topic.

Consumers and Carers (Targeted)

- Promotion of key recommendations of interest for consumers across broad and targeted media (including broad-span and social media channels)
- Education of all staff at the PANDA Helpline regarding the key recommendations and the implications for advice to consumers who may be calling the helpline
- The development of targeted social media to promote key messages and direct consumers to the guideline and companion documents
- Placement and links to Guideline and companion documents on partner organisation Web sites (e.g., beyondblue; PANDA; Pregnancy, Birth and Baby; Healthshare; Gidget Foundation Australia).

COPE has developed an email guide to pregnancy and the first year following birth for women in the perinatal period. This e-Guide (Ready to COPE) enables women to access free, fortnightly information pertaining to perinatal emotional and mental health, and contains links to guideline companion documents.

Implementation Tools

Chart Documentation/Checklists/Forms

Patient Resources

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

waiting for update

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2017 Oct

Guideline Developer(s)

Centre of Perinatal Excellence - Nonprofit Organization

Source(s) of Funding

The Centre of Perinatal Excellence (COPE) acknowledges the funding provided by the Australian Government Department of Health for the development of this guideline.

Guideline Committee

Expert Working Group (EWG)

Composition of Group That Authored the Guideline

Expert Working Group Members: Professor Marie-Paule Austin (*Chair*), Perinatal Psychiatrist, University of

New South Wales, St John of God Healthcare, Royal Hospital for Women, Black Dog Institute, Sydney, NSW; Dr Nicole Highet (*Co-chair*), Executive Director, Centre of Perinatal Excellence (COPE), Melbourne, VIC; Dr James Best, General Practitioner, GPMaroubra, Mabroubra, NSW; Mr Andrew Davis, Carer Representative and volunteer at Perinatal Anxiety and Depression Association (PANDA), Melbourne, VIC; Ms Suzanne Higgins, Credentialed Mental Health Nurse with additional qualifications in midwifery, maternal and child health and perinatal and infant mental health, St John of God Healthcare, Geelong, VIC; Dr Helen Lindner, Health psychologist, Australian Psychological Society (APS), Melbourne, VIC; Professor Rhonda Marriott, Midwife, researcher and specialist in Aboriginal and Torres Strait Islander perinatal mental health, Murdoch University, Perth, WA; Ms Creina Mitchell, Clinician, researcher and educator in maternal and child health with expertise and interest in perinatal mental health, Griffith University, Brisbane, QLD; Ms Jenni Richardson, National Helpline and Programs manager and consumer advocate for mental health and suicide prevention, PANDA, Fitzroy, VIC; Dr Vijay Roach, Obstetrician with dedicated expertise in perinatal mental health, Royal North Shore Hospital, Sydney, NSW; Ms Terri Smith, Chief Executive Officer of PANDA, Fitzroy, VIC; Dr Jan Taylor, Register midwife, midwifery academic with expertise in perinatal mental health, Canberra University, Canberra, ACT

Financial Disclosures/Conflicts of Interest

Competing Interests

Processes Used for Declaration and Management of Competing Interests

At the outset of the Guideline development process, all representatives were informed of the importance of managing competing interests and ensuring that any potential conflicts of interest were identified in advance of any meeting (as evidenced in meeting minutes). Processes put in place to manage any potential conflicts of interest were as follows:

> All Expert Working Group (EWG) members and proxies involved in the Guideline development process were required to complete a Declaration of Interest Form (as per the National Health and Medical Research Council [NHMRC] requirements). These signed and scanned forms were reviewed by the Co-Chairs of the EWG and are held by the Guideline developer.
> On sending out agenda papers, EWG members were informed of the arising agenda items and asked to notify the Chairperson in advance of the meeting of any potential conflicts of interest that had arisen since the most recent meeting.
> Any arising conflicts of interest were adjudicated by the Chair and Co-Chair. When a conflict of interest was declared by a EWG member, he or she was invited to take part and contribute to discussions but was asked to leave the room (or was not involved in email discussions) when recommendations were being formed. A conflict of interest held by the Chair was managed by the Co-Chair and the area of conflict clearly stated. The same provisions as for other members were applied.
> If a conflict of interest was deemed to be material prior to a meeting, the member was asked to continue to contribute to the committee, with the above measures taken to limit the introduction of bias.

There was only one instance of a possible competing interest – the review of a clinical psychometric instrument (the Antenatal Risk Questionnaire [ANRQ]), which was developed by one of the expert working group members. This was made known to all members of the EWG at the outset of discussions. To address this issue, the member of the group was involved in the initial discussion of all available psychometric instruments but not in further discussion or the decision-making process.

See Table B2 in the original guideline document for a list of competing interests of EWG members.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Austin M-P, Highet N, Guidelines Expert Advisory Committee. Australian clinical practice guidelines for depression and related disorders -- anxiety, bipolar disorder and puerperal psychosis -- in the perinatal period. A guideline for primary health care professionals. Melbourne (Australia): beyondblue: the national depression initiative; 2011 Feb. 108 p. [293 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the Centre of Perinatal Excellence (COPE) Web site .

Availability of Companion Documents

The following are available:

Australian perinatal mental health guideline evidence review. Technical report. Parts A-D. Melbourne (Australia): Centre of Perinatal Excellence (COPE); 2017 Jun. 381 p. Available from the Centre of Perinatal Excellence (COPE) Web site .

Australian perinatal mental health guideline evidence review. Appendix to technical report part C. Melbourne (Australia): Centre of Perinatal Excellence (COPE); 2017 Jun. 101 p. Available from the COPE Web site .

Australian perinatal mental health guideline evidence review. Appendix to technical report part D. Melbourne (Australia): Centre of Perinatal Excellence (COPE); 2017 Jun. 485 p. Available from the COPE Web site .

Effective mental health care in the perinatal period: Australian clinical practice guideline. Administrative report. Melbourne (Australia): Centre of Perinatal Excellence (COPE); 2017 May. 9 p. Available from the COPE Web site .

The Edinburgh Postnatal Depression Scale (EPDS) and Antenatal Risk Questionnaire (ANRQ) are available in the original guideline document .

Additional resources, an including online training program, are available from the COPE Web site .

Patient Resources

The following are available:

Antenatal mental health factsheets and resources. Melbourne (Australia): Centre of Perinatal Excellence (COPE); 2017. Available in from the Centre of Perinatal Excellence (COPE) Web site .

Postnatal mental health factsheets and resources. Melbourne (Australia): Centre of Perinatal Excellence (COPE); 2017. Available from the COPE Web site .

Ready to COPE guide. Melbourne (Australia): Centre of Perinatal Excellence (COPE); 2017. Available from the COPE Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on May 21, 2013. The information was verified by the guideline developer on June 17, 2013. This summary was updated by ECRI Institute on May 24, 2016 following the U.S. Food and Drug Administration advisory on Olanzapine. This summary was updated by ECRI Institute on October 21, 2016 following the U.S. Food and Drug Administration advisory on opioid pain and cough medicines combined with benzodiazepines. This summary was updated again by ECRI Institute on May 23, 2018. The information was verified by the guideline developer on June 6, 2018.

This NEATS assessment was completed by ECRI Institute on May 10, 2018. The information was verified by the guideline developer on June 6, 2018.

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